

U.S. Serial No. 10/001,396

Amendment to Office Action dated October 18, 2004

**REMARKS/ARGUMENTS**

The preceding amendments and following remarks are submitted in response to the non-final Office Action mailed October 18, 2004, setting a three-month shortened statutory period for response ending January 18, 2005. With this Amendment, claims 1, 3-5, 25, 27, 71, and 78 have been amended, and claim 2 has been cancelled. Reconsideration, examination and allowance of all pending claims are respectfully requested.

**Information Disclosure Statement**

In paragraph 1 of the Office Action, the Examiner states that the information disclosure statement (IDS) submitted on June 18, 2004 was acknowledged and considered. Applicants note, however, that a copy of the initialized Form 1449 was not provided with the Office Action. As such, Applicants request that the Examiner promptly provide a copy of the signed IDS in accordance with MPEP § 609.

**35 U.S.C. § 112 Rejections**

In paragraph 3 of the Office Action, the Examiner rejected claims 71-73 and 75-80 under 35 U.S.C. § 112, second paragraph, stating that these claims are indefinite for failing to particularly point and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner states that it is unclear whether these claims intend to claim the proximal stop mechanism/locking mechanism alone or as a system comprising the combination of a guide wire, a device, and a one-way translation member/sleeve with means for releasably locking.

In response to this rejection, Applicants have amended independent claims 71 and 78 to clarify Applicants' intent to claim the proximal stop mechanism and locking mechanism alone. In particular, claim 71 has been amended to now recite that the proximal stop

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mechanism comprises a one-way translational member affixed to the guide wire and is configured to allow the device to translate only distally over the one-way translation member. In addition, claim 78 has been amended to now recite that the locking mechanism comprises a sleeve member slidably disposed over a distal portion of the guide wire and including a means for releasably locking the translational position of the device along the guidewire. Applicants respectfully assert that these amendments to claims 71 and 78 overcome the Examiner's indefiniteness rejection of claims 71-73 and 75-80 under 35 U.S.C. § 112, second paragraph.

### 35 U.S.C. § 102 Rejections

In paragraph 5 of the Office Action, the Examiner rejected claims 1-6, 25-30, 71-73 and 78-80 under 35 U.S.C. § 102(e) as being anticipated by *Khosravi* (U.S. Patent No. 6,129,739). Applicants respectfully traverse this rejection.

The *Khosravi* reference discloses a vascular device (130) including a guidewire (132) and a sheath (143) that supports a support hoop (135) and blood permeable sac (136). As shown in Figure 11A, a set of stops (145,146) disposed on the guidewire (132) prevent the sheath (143) from translating along the length of the guidewire (132). According to col. 10, lines 26-28 of *Khosravi*, the "[s]heath 143 may rotate with respect to guide wire 132 but is translationally restrained by stops 145 and 146, for example, solder beads". See also *Khosravi* at col. 9, lines 24-26.

In contrast, amended claim 1 of the present application recites:

1. (Currently Amended) An intravascular embolic protection system comprising:  
a guide wire;  
an embolic filter *slidably* engageable over the guide wire; and  
a means for limiting translation of the embolic filter over the guide wire, the means for limiting comprising a first stop mechanism located proximal to the embolic filter when the embolic filter is operatively engaged

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*over the guide wire, said first stop mechanism configured to limit proximal translation of the embolic filter along the guidewire.*

As can be seen above, claim 1 now recites that the embolic filter is slidably engageable over the guidewire, and that the first stop mechanism is configured to limit proximal translation of the embolic filter along the guidewire. Antecedent support for these amendments can be found on pages 12-13 of the specification, and in Figures 1A-1G.

Unlike the system recited in claim 1, the *Khosravi* reference fails to disclose or suggest an embolic filter slidably engageable along the guidewire and including a first stop mechanism configured to limit proximal translation of the embolic filter along the guidewire. In contrast, *Khosravi* appears to disclose the opposite arrangement: *i.e.* a sheath that is translationally restrained by the stops, thereby preventing the ability of the sheath to slide along the guidewire, as recited in claim 1. As such, Applicants respectfully assert that the *Khosravi* reference does not anticipate the system of claim 1.

Because claim 1 is allowable, Applicants respectfully assert that dependent claims 3-11 and 25-27 are also allowable for the reasons stated above and since they add other significant elements to distinguish them from the cited prior art.

With respect to the rejection of independent claim 28, Applicants respectfully assert that the *Khosravi* reference does not disclose or suggest a sheath that is translatable from a proximal end of a guide wire to a point where an open proximal end of the sheath is distal of the guide wire stop mechanism. In contrast, and as described above, the *Khosravi* reference appears to suggest a sheath that is translationally restrained by a set of stops. See *Khosravi* at col. 9, lines 24-26; col. 10, lines 26-28; Figures 8 & 11A. Since the *Khosravi* reference fails to disclose or suggest a sheath that is translatable on the guide wire, Applicants respectfully assert that claim 28 is also patentable over the *Khosravi* reference.

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Because claim 28 is allowable, Applicants respectfully assert that dependent claims 29-30 are also allowable for the reasons stated above and since they add other significant elements to distinguish them from the cited prior art.

Turning now to the rejection of claims 71-73 and 78-80, Applicants respectfully assert that the *Khosravi* reference similarly fails to disclose each and every element of those claims. Claim 71, as amended, recites a proximal stop mechanism comprising a one-way translation member affixed to a guide wire and configured to allow translation of a device only distally over the one-way translation member. Amended claim 78, in turn, recites a locking mechanism comprising a sleeve member slidably disposed over a distal portion of a guidewire, and including a means for releasably locking the translational position of a device along the guidewire. Since the *Khosravi* reference fails to disclose the translation of a device and/or sleeve over the guide wire, as described above, Applicants respectfully assert that claims 71 and 78 are not anticipated under 35 U.S.C. § 102(e).

Because claims 71 and 78 are allowable, Applicants respectfully assert that dependent claims 72-73 and 78-80 are also allowable for the reasons stated above and since they add other significant elements to distinguish them from the cited prior art.

Claims 71-72 and 75-80 were further rejected in paragraph 5 of the Office Action under 35 U.S.C. § 102(e) as being anticipated by *Daniel et al.* (U.S. Patent No. 6,171,321). Applicants respectfully traverse this rejection.

With respect to claims 71-72, Applicants assert that *Daniel et al.* do not disclose or suggest, among other things, a one-way translation member configured to allow a device to translate only distally over the one-way translation member. In *Daniel et al.*, the tapered insert (58) is not affixed to the guide wire (26), as recited in claim 71, but is instead movably

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disposed along the guide wire (26). Moreover, the "device" (*i.e.* the filter 21) in *Daniel et al.* is separate from the sleeve (52), and is not capable of translating distally over the tapered insert (58), as is further recited in claim 71. Because *Daniel et al.* does not disclose or suggest each and every element of claim 71, Applicants respectfully assert that claims 71-72 are not anticipated under 35 U.S.C. § 102(e).

With respect to the rejection of claims 78-80, Applicants note that nothing in the *Daniel et al.* reference appears to disclose or suggest a sleeve member that includes a means for releasably locking the translational position of the device (*i.e.* the filter 21) along the guidewire (26). Instead, in *Daniel et al.* it is the tapered insert (58) that provides the necessary means to restrict movement of the filter (21) along the guidewire (26). Accordingly, Applicants respectfully assert that claims 78-80 are not anticipated by the *Daniel et al.* reference.

#### **Allowable Subject Matter**

In paragraph 6 of the Office Action, the Examiner states that claims 7-11 and 31-33 are objected to as being dependent upon a rejected base claim, but would otherwise be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The Examiner further states that the prior art fails to disclose the deformable one-way translation member as claimed.

Applicants respectfully submit that since claim 1 is in condition for allowance, claims 7-11 are also allowable. Moreover, since claim 28 is in condition for allowance, claims 31-33 are also allowable.

In view of the foregoing, Applicants respectfully assert that all pending claims are in condition for allowance. Reexamination and reconsideration are respectfully requested. If a

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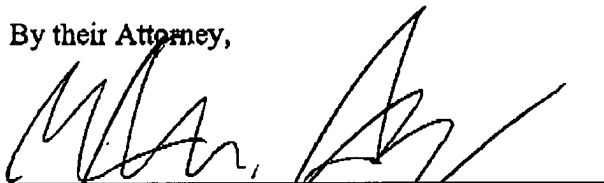
telephone conference might be of assistance, please contact the undersigned attorney at (612)  
677-9050.

Respectfully submitted,

AMR SALAHIEH ET AL.

By their Attorney,

Date:

Dec. 23, 2004

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